UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,650	02/19/2004	Robert Bargatze	MONT-038/03	2153

58249 7590 10/06/2006

COOLEY GODWARD KRONISH LLP
THE BROWN BUILDING - 875 15TH STREET, NW
SUITE 800
WASHINGTON, DC 20005-2221

EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 10/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/780,650	BARGATZE ET AL.	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *55-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *55-80* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1. The preliminary amendment filed August 4, 2004 has been entered. The examiner acknowledges the amendments to the specification. Claims 1-54 have been cancelled. Claims 55-80 have been newly entered.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

A. Claims 55-76 are drawn to a method for identifying pathogen-ligand adhesive interactions under shear flow conditions wherein the ligand is immobilized on a substrate and an isolated anti-adhesive monoclonal antibody, classified in class 435, subclass 7.1.

B. Claim 77 is drawn to an isolated adhesive peptide, classified in class 424, subclass 9.34.

C. Claim 78 is drawn to an isolated pathogen adhesin, classified in class 424, subclass 278.1.

D. Claims 79-80 are drawn to a method of developing vaccine, therapeutic or diagnostic reagent candidates, classified in class 424, subclass 184.1.

3. The inventions are distinct, each from the other because of the following reasons:

(i) Inventions B and C are patentably different products. The inventions are distinct, each from the other because of the following reasons: Although there are no provisions under the section for "Related Inventions" in M.P.E.P. 806.05 for inventive groups that are directed to different products; restriction is deemed to be proper

because these products appear to constitute patentably distinct inventions. Group B is drawn to an adhesive peptide, and Group C is drawn to a pathogen adhesin. The groups are directed to products which are distinct physically, structurally and functionally, and are therefore patentably distinct, each group from the other. For instance, the product of Group B is a unlike the peptide of Group B. Thereby, making the product of Group B distinct from the products of Group C. Therefore, one product is not required to practice the other. Each group comprises separate and distinct products that are not disclosed as being essential to the utility of the invention.

Furthermore, searching the inventions of Groups B-C would impose a serious search burden. The inventions have a separate status in the art as shown by their distinct structure. Thus different products require different searches. An amino acid sequence search of the peptide is not necessary for a determination of novelty and unobviousness of another unrelated pathogen adhesin. Moreover, a search for the Group B is not required to identify the pathogen adhesin of Group C. Furthermore, the product of Group B may be known even if the pathogen adhesion of Group C is novel. In addition, the technical literature search for the peptide of Group B and the product of Group C are not coextensive, e.g., the peptide of Group B may be characterized in the technical literature prior to discovery of the pathogen adhesion of Group C.

(ii) Inventions A and D are related as distinct methods. The methods are distinct as claimed because they have different methods with different method steps; different functions and the effects have different final outcomes. Group A is drawn to a method for identifying pathogen-ligand adhesive interactions under shear flow conditions

wherein the ligand is immobilized on a substrate. The method of Group D has a different function, developing vaccine, therapeutic or diagnostic reagent candidates. The method of Group A does not produce the same results. Each group produces different effects and different functions when compared to the other group. Therefore, the inventions are unrelated.

Searching the inventions of Groups A and D together would impose serious search burden. The inventions of Groups A and D have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the method of identification and method of development are not coextensive. For instance, search drawn to the method of identification, will not necessarily encompass searching for the efficacy of a vaccine, therapeutic or diagnostic reagent. In contrast, the search for Group D would require a text search for the method of development and prior art which teaches the inducement of an antibody response would not necessarily be applicable to the method of identification. Moreover, even if the method of identification were known, the method of development may be novel and unobvious in view of the preamble or active steps.

(iii) Inventions A and either of B-C are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The instant specification does not disclose that the method of identification would be used together with the products of B-C. The method for identifying pathogen-ligand adhesive interactions under shear flow conditions wherein the ligand is

immobilized on a substrate, are all unrelated as they comprise distinct steps and do not utilize either the peptide and adhesion which demonstrates that the method has a different mode of operation. Therefore, the method of identification does not use either of the products. Therefore, the inventions A and either B or C are unrelated because the products of Groups B or C are not used or otherwise involved in the method of Group A.

Searching the inventions of Groups A, B and C together would impose serious search burden. The inventions of Groups A, B and C have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the method of identification and the products are not coextensive. For instance, search drawn to the method of identification, will not necessarily encompass searching for the peptide or adhesin. In contrast, the search for Group C would require a text search which would not necessarily be applicable to the method of identification. Moreover, even if the method of identification were known, the peptide or adhesion may be novel and unobvious.

4. Because these inventions are distinct for the reasons given above, Groups A-D have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, A. Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
September 27, 2006